COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 13-VI-2007
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NOT FOR PUBLICATION

COMMISSION DECISION

of 13-VI-2007

amending the marketing authorisation for "PegIntron - Peginterferon alfa-2b", a medicinal product for human use, granted by Decision C(2000)1407

(ONLY THE FRENCH, DUTCH TEXT IS AUTHENTIC)

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the first subparagraph of Article 6(10) thereof,

Having regard to the application(s) submitted by Schering Plough Europe on 15 September 2006 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], and in particular Article 61(3) thereof,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 26 April 2007,

Whereas:

(1) An examination of the major variation(s) type II to the terms of the marketing authorisation for the medicinal product "PegIntron - Peginterferon alfa-2b", which is entered in the Community Register of Medicinal Products under number(s) EU/1/00/131/001-050 and the placing on the market of which was authorised by Decision C(2000)1407 of 25 May 2000, has shown that the product remains in

[1] OJ L 136, 30.4.2004, p. 1, Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).
[2] OJ L 159, 27.6.2003, p. 24.
[3] OJ L 311, 28.11.2001, p. 67, Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).

compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4].

(2) It is therefore appropriate to accept the application(s) in respect of (a) major variation(s) to the terms of the marketing authorisation and to amend Decision C(2000)1407 accordingly.

(3) Schering Plough Europe submitted, under Article 61(3) of Directive 2001/83/EC, a notification(s) for changes to an aspect of the labelling or the package leaflet, which has (have) not yet been included in Decision C(2000)1407 of 25 May 2000.

(4) The marketing authorisation should be updated, and Decision C(2000)1407 amended accordingly.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2000)1407 is amended as follows:

1) The following list of notifications for changes to an aspect of the labelling or the package leaflet is added to the updated marketing authorisation;

Application number	Annex (EU numbers affected)
EMEA/H/C/280/N/0071	IIIB (EU/1/00/131/001-050)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Schering Plough Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België.

Done at Brussels, 13-VI-2007

For the Commission
Heinz ZOUREK
Director-General

[4] OJ L 311, 28.11.2001, p. 67, Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).